

**REMARKS****Claim Status**

Claims 1 to 21 are pending. Claims 3, 4, and 8 to 21 have been withdrawn from consideration. Claims 1, 2, and 5 to 7 are amended.

**Amendments**

The specification has been amended to provide updated citation information for references cited in Applicants' disclosure.

Claims 1, 2, and 5 to 7 have been amended to specifically recite TLR7-mediated cellular activity. The amendment is fully supported throughout the specification at, for example, page 12, lines 3-14.

Claim 1 also has been amended to specifically recite contacting a test compound with cells having at least one TLR7-mediated cellular activity, an inherent aspect of any assay useful for performing the claimed method. In addition to being an inherent part of any useful assay, the amendment is supported at, for example, from page 29, line 11 through page 31, line 8.

Claim 1 has been further amended to recite that a test compound can be identified as a compound that selectively modulates at least one TLR7-mediated cellular activity of a plurality of TLR7-mediated cellular activities if the test compound modulates a first TLR7-mediated cellular activity to an at least about two-fold greater extent than it modulates a second TLR7-mediated cellular activity. The amendment is supported at, for example, Table 3, pages 31 and 32, which provides data identifying selectively modulating compounds. Each compound modulates one activity to an extent that is at least about two-fold greater than it modulates the other activity—the smallest fold increase being 2.125-fold (IRM5).

No new matter is introduced by these amendments.

**§ 112 Rejections**

Claims 1, 2, and 5 to 7 stand rejected under 35 USC § 112, first paragraph, as failing to enable one skilled in the art to make or use the invention commensurate with the scope of the claims.

The claims are amended herein to recite TLR7-mediated cellular activities, acknowledged in the Office Action as being enabled by Applicants' disclosure, obviating the rejection.

Applicants submit that the claims satisfy the requirements of 35 USC § 112, first paragraph, and respectfully request that the rejection of claims 1, 2, and 5 to 7 be withdrawn.

Claims 1, 2, and 5 to 7 stand rejected under 35 USC § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter that Applicants regard as the invention. Specifically, the Office Action states that the claim terms do not apprise one skilled in the art of the scope of cellular activities encompassed by the claims.

The claims have been amended to recite TLR7-mediated cellular activities. Applicants submit that those skilled in the art of immunology are apprised of the full scope of the cellular activities encompassed by the claims.

Applicants submit that the claims satisfy the requirements of 35 USC § 112, second paragraph, and respectfully request that the rejection of claims 1, 2, and 5 to 7 be withdrawn.

Claims 1 and 2 stand rejected under 35 USC § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter that Applicants regard as the invention. Specifically, the Office Action states that the terms "selectively modulates" and "different extent" are relative terms that render the claims indefinite.

Claim 1 has been amended to recite that a test compound is identified as a compound that selectively modulates at least one cellular activity of a plurality of TLR7-mediated cellular activities if the test compound modulates the first TLR7-mediated cellular activity to an at least two-fold greater extent than it modulates the second TLR7-mediated cellular activity.

Applicants submit that claims 1 and 2 satisfy the requirements of 35 USC § 112, second paragraph, and respectfully request that the rejection of claims 1, 2, and 5 to 7 be withdrawn.

### **§ 102 Rejections**

Claims 1, 2, and 5 to 7 stand rejected under 35 USC § 102(a) as being anticipated by U.S. Patent Publication No. US 2003/0023993 ("Medzhitov").

Claims 1, 2, and 5 to 7 also stand rejected under 35 USC § 102(c) as being anticipated by each of U.S. Patent No. 6,960,343 (“the ‘343 patent”) and U.S. Patent No. 7,029,861 (“the ‘861 patent”).

**Claims 1, 2, and 5 to 7 are patentable over Medzhitov and the ‘343 patent**

The Medzhitov reference has issued as the ‘343 patent. Consequently, both references describe the Toll/Interleukin-1 receptor protein (TIRAP) and experiments involving activation of TLR4 with LPS. Neither Medzhitov nor the ‘343 patent describes methods involving the identification of compounds that selectively modulate TLR7-mediated cellular activities. Therefore, neither Medzhitov nor the ‘343 patent can anticipate Applicants’ claims, as amended herein.

Applicants respectfully request withdrawal of the rejections of claims 1, 2, and 5 to 7 under 35 U.S.C. § 102(a) and 35 U.S.C. § 102(c) over Medzhitov and the ‘343 patent, respectively.

**Claims 1, 2, and 5 to 7 are patentable over the ‘861 patent**

The ‘861 describes methods of screening for TLR4 inhibitory or stimulatory compounds, using a method that is asserted to anticipate Applicants’ claims. Applicants respectfully submit that the ‘861 patent fails to anticipate claims 1, 2, and 5 to 7.

As amended herein, Applicants’ claims are now directed to TLR7-mediated cellular activities. The ‘861 patent, like Medzhitov and the ‘343 patent discussed above, reports only TLR4-mediated cellular responses. The ‘861 patent fails to describe methods involving the identification of compounds that selectively modulate TLR7-mediated cellular activities. Consequently, the ‘861 patent can not anticipate Applicants’ claims.

Applicants respectfully request withdrawal of the rejections of claims 1, 2, and 5 to 7 under 35 U.S.C. § 102(c) over the ‘861 patent.

**CONCLUSION**

In view of the above, it is submitted that the application is in condition for allowance. Reconsideration of the application is requested.

Allowance of claims 1, 2, and 5 to 7, as amended, at an early date is solicited.

Respectfully submitted,

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